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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,293	12/22/2000	James Wilkie	SSI-011	2615

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EXAMINER

TELLER, ROY R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 01/08/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,293

Applicant(s)

WILKIE ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,42,49-51,56-62,82-86,89,90 and 97 is/are pending in the application.
- 4a) Of the above claim(s) 2,42,49-51 and 56-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 82-86,89,90 and 97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of group II in paper # 7, received 12/24/02, is acknowledged. The traversal is on the grounds that the close relationship of claims under group III and group II are based upon a common novel feature in the form of a composition of a protein-based tissue sealant or adhesive. This is not found persuasive because a search of group II would not necessarily include the composition of a protein-based tissue sealant or adhesive. In addition, a search for the invention of group II would not be a complete and thorough search of the pertinent patent and non-patent technical literature. For example, the composition of group III is differently searched and classified from group II.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 82-86, 89-90, and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrows (USPN 5,583,114) in view of Courey (USPN 6,162,241).

The claimed invention is drawn to a platelet-free composition for use as a tissue sealant or adhesive comprising a protein solution and at least one preparation selected from the group

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consisting of a surfactant preparation and a lipid preparation. The protein is selected from the group consisting of albumin, collagen, gelatin, elastin, protamine, and histone. The protein concentration is between about 3% (w/w) and 50% (w/w). The surfactant concentration is between about 0.05% (w/w) and about 10% (w/w).

Barrows teaches an adhesive composition which may be used to bond or seal tissue in vivo (see abstract). Barrows adhesive composition consists of two components mixed together, the first is a protein, preferably a serum albumin protein consisting of about 20%-60% wt/vol. (column 19, claim 1). The second component of the mixture is a water-soluble crosslinking agent (see abstract). Barrows does not teach the composition as comprising a surfactant.

Courey teaches a composition comprising a surfactant to form a barrier to blood leakage by mechanical means not directly related to the natural clotting mechanism (column 7, lines 27 and 20-22). Absent some evidence to the contrary, the claimed amount constitutes routine optimization of a known composition.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have added the surfactant of Courey to the composition disclosed by Barrows in order to enhance the tissue sealant or adhesive properties of the composition to form a barrier by mechanical means not directly related to the natural clotting process. While Courey does not specifically teach the concentration of surfactant, absent some evidence to the contrary, the surfactant disclosed by Courey would inherently possess this property.

Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barrows in view of Courey, and Soon-Shiong (USPN 5,700,848).

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The claimed invention is as described above, wherein the composition comprises a protein solution with a concentration between about 3% (w/w) and 50% (w/w) and at least one preparation selected from the group consisting of a surfactant preparation with a concentration between about 0.05% (w/w) and about 10% (w/w) and a lipid preparation.

Barrows in view of Courey teach a composition comprising serum albumin protein consisting of about 20%-60% wt/vol. with a water-soluble crosslinking agent and a surfactant. Barrows in view of Courey does not teach a lipid in this composition.

Soon-Shiong teaches a lipid used in bioadhesives and wound dressings (see abstract). Kim teaches of biocompatible materials in bioadhesives and wound dressings (see abstract).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have formulated the composition of Barrows in view of Courey to comprise a lipid, based on the disclosure of Soon-Shiong, because Soon-Shiong teaches the use of biocompatible materials in bioadhesives and wound dressings.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
1654
1/7/2003

RT

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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